REMARKS

In response to the Office Action of February 9, 2007, claims 19, 22 and 23 have been amended, claim 31 has been canceled and new claims 46-58 have been added. Claims 22 and 23 were rejected under 35 U.S.C. § 112, second paragraph; claim 19 was rejected under 35 U.S.C. § 112, first paragraph; and claims 19-32 were rejected under 35 U.S.C. § 103(a). Each of the rejections is addressed below.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 22 and 23 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Specifically, the Examiner maintains that the phrase "wherein X is selected from" has insufficient antecedent basis. In response to this rejection claims 22 and 23 have been amended to read "wherein $\underline{X}$ is selected from." In light of the amendment to claims 22 and 23, Applicant believes that proper antecedent basis has been established and respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph (enablement)

The first paragraph of Section 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971).

The Examiner has rejected claim 19 under the first paragraph of Section 112 on the basis that the Specification does not enable the prevention of diseases and conditions. Although Applicant does not acquiesce to this rejection, in the interest of furthering the prosecution of this case, independent claim 19 has been amended without prejudice by deleting this term and new claims 46-58 have been added. Applicant reserves the right to prosecute claims directed to the deleted subject matter in a timely filed continuing application.

New claim 46 is drawn to diseases and conditions of the skin other than those specifically set forth in new claims 47 and 53. Support for this claim can be found in various places in the Specification, see e.g., page 16, line 22 to page 17, line 3.

New independent claim 47 is drawn to a pharmaceutical composition for the prevention and treatment of inflammatory conditions and skin damage resulting from exposure to skin irritants. Support for this claim can be found in Example 11 (page 46) and Figure 13 of the Specification. With reference to Example 11 and Figures 13, it can be seen that topical application of Soliprin™ (a mixture of Free-B-Ring flavonoids and flavans blended in an 80:20 ratio) both before and after application of the skin irritant arachidonic acid (AA) to the ears of mice, significantly reduced inflammation as compared to the control group. Applicant maintains that this Example supports use of the pharmaceutical composition for both the prevention and treatment of damage resulting from exposure to skin irritants.

New independent claim 53 is drawn to a pharmaceutical composition for the prevention and treatment of sunburns and skin damage resulting from exposure to UV radiation. Support for this claim can be found in the Example 12 (pages 47-48) and Figure 15 of the Specification. With reference to Example 12 and Figure 15, it can be seen that topical applications of Soliprin™, both before and after UV radiation, significantly reduced erythema scores as compared with the control group and the group that was administered the standard treatment agent Sooth-a-caine. Additionally, the best results were achieved by treatment with 5 mg/mL Soliprin™ before irradiation. Applicant maintains that this Example supports use of the pharmaceutical composition for both the prevention and treatment of damage resulting from exposure to UV radiation.

Applicant maintains that independent claim 19, as amended, and new independent claims 47 and 53 comply with the enablement requirement and as such Applicant respectfully requests that the Examiner reconsider this rejection.

Rejections under 35 U.S.C. § 103(a)

The Examiner bears the burden of establishing a prima facie case of obviousness. In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 USPQ2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

> whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success. . . . Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

In re Dow Chemical, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

The Examiner has rejected claims 19-32 under 35 U.S.C. § 103(a) as being unpatentable over Xu (U.S. Pat. No. 6,083,921) in view of Zhou (U.S. Pat. No. 6,319,523). The Examiner reasons that Xu teaches a pharmaceutical composition comprised of baicalin for antibacterial purposes and Zhou teaches a pharmaceutical composition comprised of catechin for antibacterial purposes. From this the Examiner concludes that one of ordinary skill in the art would have been motivated to modify Xu's pharmaceutical composition to include the active ingredient in Zhou because the combined references would create an improved pharmaceutical composition. In response to this rejection, claim 19 has been amended without prejudice and claims 46-58 have been added. Applicant reserves the right to prosecute claims directed to the deleted subject matter in a timely filed continuing application.

Support for new claims 46-58 is described in detail above. As amended, claim 19 is drawn to a pharmaceutical composition for topical application to the skin for use in the treatment of diseases and conditions related to the skin comprised of a mixture of Free-B-Ring flavonoids and flavans, comprising at least baicalin and catechin. Support for these amendments can be found throughout the Specification, particularly in Examples 9 and 11-14. More specifically, Example 9 (pages 43-45), describes the preparation of a composition of matter referred to as Soliprin™. With reference to Table 10 (page 44) it can be seen that Soliprin ™ is comprised of 86% total active ingredients of which approximately 62% is the Free-B-Ring flavonoid baicalin

and 10% is the flavan catechin. As provided in the Specification, the composition of matter set forth in Table 10 was obtained by blending a standardized extract of *Scutellaria baicalensis* having a total Free-B-Ring Flavonoid content of approximately 82% (w/w) and a standardized extract of *Acacia catechu* having a total flavan content of approximately 80% (w/w) in a ratio of 85:15 (page 43, lines 20-30). As further provided in Example 9, the blending ratio of these two extracts can be altered to provide any number of various compositions of matter (page 44, line 3 - page 45, line 3. In fact, the composition used in the Examples to exemplify the method of the instant invention had a blending ratio of 80:20 (see e.g., Example 11, page 46 and Example 12, page 47). It is clear, however, that regardless of the blending ratio the primary active components of the composition will be baicalin and catechin. Further, even though the method of the invention is demonstrated using only one embodiment of the composition for illustrative purposes, Applicant maintains that the effectiveness of the method can be extended to other embodiments in which the composition is comprised of the primary active ingredients baicalin and catechin. Regarding topical application to the skin, Example 13 describes the formulation of Soliprin ™ into a cream and Example 14 demonstrates the safety and efficacy of topical application of this formulation to the skin. Applicant maintains that the claims as amended are supported by the Specification.

Xu teaches a pharmaceutical composition for use in preventing and treating viral or bacterial infections or for use in enhancing the immune response. The composition is comprised of a combination of plant extracts, wherein the combination of extracts includes at least one plant from each of the genuses of Labiatae, Caprifoliaceae and Oleaceae (Xu, col. 1, lines 45-52). In one embodiment, the pharmaceutical composition is comprised of baicalin, chlorogenic acid and forsythiaside (Xu, col. 5, lines 48-50). Xu teaches that the composition may be administered in a number of ways, none of which include topical application to the skin (Xu, col. 10, lines 45-53). The instant invention, on the other hand, as set forth in independent claim 19, as amended, is drawn to a pharmaceutical composition of matter for topical application to the skin for use in the treatment of diseases and conditions related to the skin, wherein the composition is comprised of

a mixture Free-B-Ring flavonoids and flavans, comprising at least baicalin and catechin. In one embodiment, the mixture of Free-B-Ring flavonoids is isolated from a plant or plants in the *Scutellaria* genus of plants and the mixture of flavans is isolated from a plant or plants in the *Acacia* genus of plants. Xu does not teach or suggest a pharmaceutical composition comprised of a mixture of Free-B-Ring flavonoids and flavans and more specifically Xu does not teach or suggest a composition comprised of at least baicalin and catechin. Nor does Xu teach or suggest a pharmaceutical composition for treatment of diseases and conditions related to the skin which can be topically applied. Applicant further asserts that the Xu reference does not teach or suggest the prevention or treatment of any of the specific diseases and conditions set forth in new claim 46. As such, Applicant maintains that the Xu reference does not render the composition of claim 19 or claims 20-46 which depend therefrom obvious.

New claim 47 is drawn to a pharmaceutical composition comprised of at least one Free-B-Ring flavonoid and one flavan for use in the prevention and treatment of inflammatory conditions and skin damage resulting from exposure to skin irritants. As detailed above, Applicant maintains that Xu does not teach or suggest either this composition of matter or its intended use. As such, Applicant maintains that the Xu reference does not render the composition of new claim 47, nor the claims which depend therefrom obvious.

Finally, new claim 53 is drawn to a pharmaceutical composition comprised of at least one Free-B-Ring flavonoid and one flavan for use in the prevention and treatment of sunburns and skin damage resulting from exposure to UV radiation. Again as detailed above, Applicant maintains that Xu does not teach or suggest either this composition of matter or its intended use. As such, Applicant maintains that the Xu reference does not render the composition of new claim 53, nor the claims which depend therefrom obvious.

Zhou teach a composition for inhibiting oral bacterial comprised of a polyphenol derivative, preferably a catechin derivative and at least one compound selected from the group consisting of a mogroside derivative composition, licorice extract and combinations thereof (Zhou, col. 1, lines 40-48). Zhou teaches that the composition may be administered in a number

of ways, none of which include topical application to the skin (Zhou, col. 4, lines 31-36). As detailed above, the claims of the instant invention are drawn to a pharmaceutical composition of matter for topical application to the skin for use in the prevention and treatment of diseases and conditions related to the skin, wherein the composition is comprised of a mixture Free-B-Ring flavonoids and flavans, comprising at least baicalin and catechin. Zhou does not teach or suggest such a composition. Nor does Zhou teach or suggest a pharmaceutical composition for treatment of diseases and conditions related to the skin which can be topically applied. Rather, Zhou teaches a composition of matter intended for use as an inhibitor of oral bacteria, which is administered primarily orally as a beverage, drop, oral rinse, toothpaste and the like. Applicant further asserts that the Zhou reference does not teach or suggest the prevention or treatment of any of the specific diseases and conditions set forth in new claims 46, 47 or 53. As such, Applicant maintains that the Zhou reference does not render the compositions of claims 19-58 of the instant invention obvious. Nor does Zhou cure the defects of the Xu reference. Applicant therefore maintains that this combination of references therefore does not render the claims of the instant invention obvious and respectfully requests that the Examiner reconsider this rejection.

If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

May 9, 2007

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